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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte TODD K. WHITEHURST, JAMES P. MCGIVERN, CARLA MANN WOODS, and JANUSZ A. KUZMA

Appeal 2008-1282
Application 10/057,116
Technology Center 3700

Decided: May 21, 2008

Before DONALD E. ADAMS, RICHARD M. LEBOVITZ, and JEFFREY N. FREDMAN, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to methods for treating patients with chronic pain using electrical stimulation which the Examiner has rejected as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm in part, reverse in part and enter new grounds of rejection.

Background

"Neuropathic pain is the result of a malfunction somewhere in the nervous system. The site of the nervous system injury or malfunction can be either in the peripheral or in the central nervous system" (Spec. 1). The Specification notes that "[c]ommon symptoms include tingling, prickling or numbness; the sensation of wearing an invisible 'glove' or 'sock'; burning or freezing pain; sharp, jabbing or electric pain; extreme sensitivity to touch; muscle weakness; and loss of balance and coordination" (Spec. 2). The Specification discloses that "[s]ignificant research has been performed over the past 30 years evaluating the use of peripheral nerve stimulation for the management of refractory chronic peripheral pain" (Spec. 7).

Statement of the Case

The Claims

Claims 4-6, 8, 15, 16, 20 and 27 are on appeal. We will focus on claims 4, 8, 15 and 27, which are representative and read as follows:

> 4. A method for treating a patient with chronic pain, comprising:
>
> identifying a patient experiencing sensations of chronic pain;
>
> providing at least one leadless stimulator having at least two electrodes;
>
> implanting the at least one leadless stimulator adjacent to at least one peripheral nerve of the patient, said peripheral nerve being responsible at least in part for the sensations of chronic pain experienced by the patient;
>
> generating stimulation pulses within the at least one leadless stimulator in accordance with stimulation parameters; and

delivering the stimulation pulses from the electrodes of the at least one leadless stimulator to the at least one peripheral nerve of the patient for the purpose of reducing the sensations of chronic peripheral pain experienced by the patient;

wherein the leadless stimulator has a size and shape suitable for placement of the electrodes adjacent to the at least one peripheral nerve;

wherein the at least one peripheral nerve comprises at least one of an intercostal nerve, an intercostal nerve branch, a greater occipital nerve, a lesser occipital nerve, and a third occipital nerve.

8. A method for treating a patient with chronic pain, comprising:

identifying a patient experiencing sensations of chronic pain;

providing at least one leadless stimulator having at least two electrodes;

implanting the at least one leadless stimulator adjacent to at least one peripheral nerve of the patient, said peripheral nerve being responsible at least in part for the sensations of chronic pain experienced by the patient;

generating stimulation pulses within the at least one leadless stimulator in accordance with stimulation parameters; and

delivering the stimulation pulses from the electrodes of the at least one leadless stimulator to the at least one peripheral nerve of the patient for the purpose of reducing the sensations of chronic peripheral pain experienced by the patient,

wherein the chronic pain is located in one or both lower limbs, and the at least one stimulator is implanted adjacent to at least one nerve fiber of a common peroneal nerve, a common peroneal nerve branch, a sciatic nerve, a sciatic nerve branch, a saphenous nerve, a saphenous nerve branch, a posterior cutaneous nerve, a posterior cutaneous nerve branch, a sural nerve, a sural nerve branch, an

obturator nerve, an obturator nerve branch, a femoral nerve, a femoral nerve branch, a lateral cutaneous nerve, and a lateral cutaneous nerve branch.

15. A method for treating a patient with chronic pain, comprising:

identifying a patient experiencing sensations of chronic peripheral pain, wherein the chronic peripheral pain includes at least one of chronic neuropathic pain, failed back surgery syndrome, arachnoiditis, occipital neuralgia, peripheral pelvic pain, cardiac pain and back pain;

providing at least one leadless stimulator having at least two electrodes;

providing at least one sensor;

implanting the at least one stimulator adjacent to at least one peripheral nerve of the patient, said peripheral nerve being responsible at least in part for the sensation of chronic peripheral pain experienced by the patient;

providing operating power to the at least one stimulator;

using the sensor to sense a physical condition;

determining stimulation parameters based upon the sensed condition;

generating stimulation pulses within the at least one stimulator in accordance with the stimulation parameters; and

delivering the stimulation pulses from the electrodes of the at least one stimulator to the at least one peripheral nerve of the patient for the purpose of reducing the sensations of chronic peripheral pain experienced by the patient;

wherein the stimulator has a size and shape suitable for placement of the electrodes adjacent to the at least one peripheral nerve of the patient.

27. A method for treating a patient with chronic pain, comprising:

providing at least one leadless stimulator having at least two electrodes;

implanting the at least one leadless stimulator adjacent to at least one peripheral nerve of the patient, said peripheral nerve being responsible at least in part for the sensations of chronic pain experienced by the patient;

generating stimulation pulses within the at least one leadless stimulator in accordance with stimulation parameters;

delivering the stimulation pulses from the electrodes of the at least one leadless stimulator to the at least one peripheral nerve of the patient for the purpose of reducing the sensations of chronic peripheral pain experienced by the patient; wherein the leadless stimulator has a size and shape suitable for placement of the electrodes adjacent to the at least one peripheral nerve;

transmitting data from a transmitter of said stimulator to an external device; and

transmitting said stimulation parameters to said external device.

The prior art

The Examiner relies on the following prior art references to show unpatentability:

Nelson	US 6,480,745 B2	Nov. 12, 2002
Schulman	WO 98/37926 A1	Sep. 3, 1998

Christine B. Novak and Susan E. Mackinnon, *Outcome following Implantation of a Peripheral Nerve Stimulator in Patients with Chronic Nerve Pain*, 105 Plastic and Reconstructive Surgery 1967 (2000).

The issues

The rejections as presented by the Examiner are as follows:

A. Claims 4-6, 8, 15, 16, and 20 stand rejected under 35 U.S.C. § 103(a), as being obvious over Schulman and Novak.

B. Claim 27 stands rejected under 35 U.S.C. § 103(a), as being obvious over Schulman, Novak, and Nelson.

A. 35 U.S.C. § 102(e) rejection over Schulman and Novak

It is undisputed that "the prior art teaches stimulating certain nerves to treat non-chronic pain" (App. Br. 10). Appellants do not dispute that Schulman teaches a leadless stimulator with two electrodes, implanting the electrodes adjacent to a nerve and delivering stimulation pulses to reduce pain (*see* Ans. 3, App. Br. 11-12).

According to the Examiner, because "Schulman does not limit his method to any one nerve in particular, it would have been obvious to implant the device near a peripheral nerve if the peripheral nerve required stimulation" (Ans. 4). The Examiner, however, has not provided any evidence regarding applicability of the method to the specifically claimed nerves, instead arguing that a routine physical examination would suggest applicability to the claimed nerves (*see* Ans. 8).

However, to establish a prima facie case of obviousness all the claim features must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 985 (CCPA 1974). In the instant case, there is no teaching of the claim features drawn to the specific nerves listed in claims 4 and 8 or of the specific diseases listed in claim 15. The Examiner has not provided any evidence or specific reasoning which would suggest the specific nerves or diseases of claims 4, 8, and 15. In the absence of such teachings or suggestions, the Examiner has not established a prima facie case of obviousness.

We therefore reverse the rejection of claims 4-6, 8, 15, 16, and 20 as being obvious over Schulman and Novak.

B. 35 U.S.C. § 103(a) rejection over Schulman, Novak, and Nelson

Appellants argue that "Nelson does not teach or suggest that the implanted device transmits its own stimulation parameters to an external device as recited in claim 27" (App. Br. 16). Appellants contend that "[t]o the contrary, Nelson appears only to teach that 'patient physiologic data detected by a deployed IMD 112 will be transmitted via IMDNI 116 to computer 220 for purposes of analysis of this data'" (App. Br. 16).

The Examiner responds that "Nelson et al. disclose that information in addition to physiological data may be stored and gathered for transmission to a remote information network" (Ans. 10). The Examiner further contends that "information regarding IMD (implantable medical device) operation would suggest the inclusion of stimulation parameters to anyone of ordinary skill in the art concerned with researching implant operation and treatment effectiveness" (Ans. 10-11).

In view of these conflicting positions, we frame the obviousness issue before us as follows:

Would Nelson have suggested to the ordinary person of skill in the art to transmit information such as treatment parameters from an implanted device to an external device?

Findings of Fact

1. Schulman teaches a leadless stimulator having two electrodes (Schulman 2:10-21; Fig. 2).

2. Schulman teaches implanting the stimulator adjacent to a nerve (Schulman 3:9-14) noting that "such a device is useful in a wide variety of applications to stimulate nerves and associated neural pathways, e.g., to decrease or relieve pain" (Schulman 6:11-13).

3. Schulman teaches generating stimulation pulses where "controller circuitry 106 controls the operation of the stimulation circuitry 110 using a controller 130 (preferably a state machine or microprocessor) according to configuration data within a configuration data storage 132 coupled to controller 130" (Schulman 8:31-34).

4. Schulman teaches delivering the stimulation pulses to a nerve, noting "the controller 130 commands stimulation circuitry 110 to generate a sequence of drive impulses through electrodes 112 to stimulate tissue, e.g., a nerve, proximate to the implanted location of the microstimulator 100a or 100b" (Schulman 12:6-9). Schulman notes that "a programmable pulse generator 178 and voltage multiplier 180 are configured with parameters (see Table I) corresponding to a desired pulse sequence" (Schulman 12:9-11).

5. Novak discloses peripheral nerve stimulation to treat chronic pain (*see* Novak at 1967).

6. Nelson teaches that "[a]fter implantation of an IMD . . . clinician involvement with respect to the IMD has typically only begun. The IMD usually cannot be merely implanted and forgotten, but must be

monitored for optimal results, and may require occasional adjustment of certain parameters or settings" (Nelson 2:39-44).

7. Nelson teaches that "many IMDs are capable of storing certain state information or other data regarding their operation internally in addition to physiological data" (Nelson 2:51-53).

8. Nelson teaches that "it would be desirable if data collected by an IMD could be viewed remotely" (Nelson 2:57-58).

9. Nelson teaches that if "a change, modification or reprogramming of IMDs is indicated, it would be desirable if the instruction could be implemented in the IMD as soon as possible (Nelson 2:61-63).

Discussion of 35 U.S.C. § 103(a) over Schulman, Novak, and Nelson

Schulman teaches a method to treat pain by providing a leadless stimulator with two electrodes, implanting the electrodes adjacent to a peripheral nerve, generating stimulation pulses which are delivered to the peripheral nerve (FF 1-4). Novak teaches stimulation of peripheral nerves to treat chronic pain (FF 5).

The Examiner acknowledges that Schulman and Novak do not teach transmission of stimulation parameters to an external device (Ans. 5). The Examiner relies upon Nelson for the disclosure that implantable devices may require the adjustment of certain parameters and that transmission of that data to the external device to permit rapid modifications based upon device operation is desirable (FF 6-9).

We conclude that the Examiner has set forth a prima facie case that claim 27 would have been obvious to the ordinary artisan in view of Schulman, Novak, and Nelson. In *KSR*, the Supreme Court indicated that

"[w]hen a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, §103 likely bars its patentability." *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1740 (2007). In the instant case, using Nelson's method of transmitting operational parameters between an implantable device and a remote monitoring unit in the device of Schulman would have resulted in analysis of the stimulation parameters (*see* FF 1-9).

In particular, when Nelson teaches that "information about the IMD may be gathered for treatment or research purposes. For example, many IMDs are capable of storing certain state information or other data regarding their operation internally in addition to physiological data" (Nelson 2:49-53), this directly suggests transmission of "state information" to the external device. In the stimulation device of Schulman, the central type of "state information" would be the stimulation parameters; termed pulse sequence parameters by Schulman (*see* FF 4).

We are not persuaded by Appellants' argument that "the cited combination of prior art fails to teach or suggest a method in which an implanted stimulator transmits its stimulation parameters to an external device". Nelson states that "[a]fter implantation of an IMD . . . clinician involvement with respect to the IMD has typically only begun. The IMD cannot be merely implanted and forgotten, but must be monitored for optimal results, and may require occasional adjustment of certain parameters or settings" (Nelson 2:39-44), Nelson directly suggests transmission of important parameters for monitoring (see above). An ordinary practitioner

would have applied this suggestion to the Schulman device to transmit the central data involved in electrical stimulation, the stimulation parameters (*see* FF 4). We therefore find that the prior art does suggest transmission of the stimulation parameters to an external device.

We affirm the rejection of claim 27 as obvious over Schulman, Novak, and Nelson.

New grounds of rejection

Under the provisions of 37 C.F.R. § 41.50(b), we enter the following new grounds of rejection.

Claims 4-6, 8, 15, 16, and 20 are rejected under 35 U.S.C. § 103 as obvious in view of Schulman, Novak and newly cited references.
Richard L. Weiner & Kenneth L. Reed, *Peripheral Neurostimulation for Control of Intractable Occipital Neuralgia*, 2 Neuromodulation 217 (1999).
Picaza et al., *Pain Suppression by Peripheral Nerve Stimulation*, 40 Appl. Neurophysiol. 223 (1977).
Ghoname et al., *Percutaneous Electrical Nerve Stimulation for Low Back Pain*, 281 J. Am. Medical Ass'n 818 (1999).

Novak teaches a method of treating a patient with chronic pain where "[p]atients with chronic pain caused by trauma to a peripheral nerve can be extremely challenging to treat" (Novak at 1967, col. 1), comprising:

Identifying a patient where "patients in whom pain control has not been achieved following appropriate surgical intervention for their nerve-related problem . . . should be considered for implantation of a peripheral nerve stimulator" (Novak at 1971, col. 1).

Providing a stimulator where "[s]urgical implantation of the peripheral nerve stimulator is performed in two operative procedures" (Novak at 1967, col. 2),

Novak does not teach the use of a leadless stimulator with two electrodes, nor the specific nerves listed.

Schulman teaches a leadless stimulator having two electrodes (Schulman 2:10-21; Fig. 2).

Schulman teaches implanting the stimulator adjacent to a nerve (Schulman 3:9-14) noting that "such a device is useful in a wide variety of applications to stimulate nerves and associated neural pathways, e.g., to decrease or relieve pain" (Schulman 6:11-13).

Schulman teaches generating stimulation pulses where "controller circuitry 106 controls the operation of the stimulation circuitry 110 using a controller 130 (preferably a state machine or microprocessor) according to configuration data within a configuration data storage 132 coupled to controller 130" (Schulman 8:31-34).

Schulman teaches delivering the stimulation pulses to a nerve, noting "the controller 130 commands stimulation circuitry 110 to generate a sequence of drive impulses through electrodes 112 to stimulate tissue, e.g., a nerve, proximate to the implanted location of the microstimulator 100a or 100b" (Schulman 12:6-9).

Schulman teaches that the stimulator has a size and shape suitable for placement adjacent to a peripheral nerve (Schulman 2:1-12).

With regard to claims 5-6, Schulman teaches application at less than 10 ma and less than 100 Hz (Schulman 22:15-25).

With regard to claim 16, Schulman teaches a sensor 188 coupled to the electrodes (Schulman, fig. 2).

With regard to claim 20, Schulman teaches implanting more than one stimulator (Schulman, fig. 3A).

With regard to claims 4, 15, Weiner teaches the use of peripheral neurostimulation of the occipital nerve to treat pain associated with occipital neuralgia (Weiner at 218, col. 1).

With regard to claims 4, 8, Picaza teaches application of peripheral nerve stimulation to treat pain in the sciatic nerve, the femoral nerve, peroneal nerve and occipital nerve (Picaza at 227, table III).

With regard to claim 15, Ghoname teaches application of peripheral nerve stimulation to back pain (Ghoname at 819, col. 3).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the Schulman peripheral nerve stimulation device, taught by Schulman as useful in treating peripheral nerve pain, to treat patients with chronic pain in a variety of nerves such as those disclosed by Novak, Weiner, and Picaza as well as those with chronic back pain disclosed by Ghoname, since each of Novak, Weiner, Picaza, and Ghoname teach treatment of pain by peripheral nerve stimulation. In particular, Weiner directly motivates application of the

Schulman device to the occipital nerve, since Weiner teaches that electrical stimulation of the occipital nerve will treat occipital neuralgia (Weiner at 217). Similarly, Picaza directly motivates application of the Schulman device to nerves including the sciatic nerve, the femoral nerve, and the peroneal nerve, since Picaza teaches that electrical stimulation of these nerves will help reduce pain (Picaza at 227, table III). Finally, Ghoname directly motivates application of the Schulman device to back pain, since Ghoname teaches that electrical stimulation will help treat back pain (Ghoname at 819, col. 3).

In *KSR*, the Supreme Court indicated that " [w]hen a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, §103 likely bars its patentability." *KSR v. Teleflex Inc.*, 127 S. Ct. 1727, 1740 (2007). This reasoning is applicable here, where the application of a peripheral nerve stimulation device to treat pain in certain nerves would predictably be used to treat pain from other nerves known to be treatable by peripheral nerve stimulation devices and on other diseases known to be treatable using peripheral nerve stimulation devices. We therefore conclude that claims 4-6, 8, 15, 16, and 20 are prima facie obvious over Schulman, Novak, Weiner, Picaza, and Ghoname.

CONCLUSION

In summary, we reverse the rejections of claims 4-6, 8, 15, 16, and 20 under 35 U.S.C. § 103(a) over Schulman and Novak. We affirm the rejection of 27 under 35 U.S.C. § 103(a) over Schulman, Novak, and

Nelson. This decision also contains a new grounds of rejection pursuant to 37 C.F.R. § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 C.F.R.

§ 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 C.F.R. § 41.50(b) also provides that the Appellants, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

(1) Reopen prosecution. Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the Examiner, in which event the proceeding will be remanded to the Examiner. . . .

(2) Request rehearing. Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED IN PART, REVERSED IN PART, § 41.50(b)

Ssc:

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